Molina Clinical Policy
Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities (ReWalk): Policy No. 244

Last Approval: 10/12/2022
Next Review Due By: October 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

This policy describes addresses the use of a powered exoskeleton for ambulation in patients with lower-limb disabilities on individuals who have lost the ability to ambulate independently.

An exoskeleton is an external structure with joints and linkages that can be thought of as wearable robots constructed around the shape and function of the human body. A powered exoskeleton, as defined in this evidence review, is an exoskeleton-like framework worn by a human that contains a power source that provides energy for limb movement. **Robotic lower body exoskeletons** are designed to enable individuals with lost lower limb function to walk independently. When worn, the device consists of an upper-body harness, lower-limb braces, motorized joints, ground-force sensors, a tilt sensor, and a backpack containing a computerized controller and rechargeable battery. Using a wrist-worn wireless remote control, the user commands the device to stand, sit, or walk. The user is secured with the device at the waist, along each lower extremity, and at the feet. Additionally, standard crutches are used to maintain stability.

Regulatory Status

The United Staes Food and Drug Administration (FDA) approved several robotic lower body exoskeleton devices via the 510(k) clearance **(FDA product code: PHL)** with a classification of **Class II** (considered higher risk than Class I devices and require greater regulatory controls to provide reasonable assurance of safety and effectiveness prior to US marketing).

There are several FDA approved robotic lower body exoskeleton devices on the market, including the ReWalk exoskeleton, Ekso, Ekso GT, Indego, and the ExoAtlet-II (ExoAtlet Asia Co. Ltd., Denver, CO). The FDA-approved indications for these devices include their use by patients with hemiplegia and paraplegia due to SCI or stroke when accompanied by a caregiver who has received specialized training. Additionally, they may be utilized in rehabilitation facilities. None of these items are intended for athletics or climbing stairs. For several of these devices, patients must maintain upper-extremity strength and mobility in order to utilize stabilizing crutches. **NOTE:** Brand names are used for reference purposes only and are not intended to represent an exhaustive list of all accessible devices.

The FDA has approved two motorized exoskeletons for use in the home:

- ReWalk™ (ReWalk Robotics, Inc., Yokneam, Israel)
- Indego® (Parker Hannifin, Cleveland, OH)

ReWalk™ (ReWalk Robotics)

The FDA granted ReWalk a de novo 510(k) classification (K131798) in 2014. New classification applies to this device and its generic equivalents. ReWalk (current version ReWalk Personal 6.0) is the first external, powered, motorized orthosis (powered exoskeleton) used for medical purposes that is worn over paralyzed or weakened limbs to facilitate ambulation. The ReWalk™ orthotically fits to the lower limbs and part of the upper body and is intended to enable individuals with SCI at levels T7 to L5 to perform ambulatory functions with supervision of a specially trained companion in accordance with the user assessment and training certification program. The device is also intended to enable

individuals with SCI at levels T4 to T6 to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. The ReWalk™ is not intended for sports or stair climbing. The following characteristics should be present in candidates for the device:

- Hands and shoulders can support crutches or a walker
- Healthy bone density
- Skeleton does not suffer from any fractures
- Able to stand using a device such as a standing frame
- In general good health
- Height is between 160 cm and 190 cm (5'3"-6'2")
- Weight does not exceed 100 kg (220 lb)

Rewalk Personal Systems are developed for home and in the community. The ReWalk Rehabilitation system is utilized in a clinical rehabilitation setting.

The ReWalk ReStore™, a portable, lightweight exo-suit, was approved in 2019 for the treatment of people with stroke-related lower limb disability.

Ekso™ (version 1.1) and Ekso GT™ (version 1.2) (Ekso Bionics® Inc., Richmond, CA)

Ekso and Ekso GT was authorized for marketing in 2016 via the 510(k) process (K131798). The ReWalk was the reference device. Ekso is designed to perform ambulatory functions in *rehabilitation facilities* under the supervision of a trained physical therapist for the following populations: individuals with hemiplegia due to stroke; individuals with SCIs at levels T4 to L5; individuals with SCI at levels C7 to T3.

ExoAtlet-II (ExoAtlet Asia Co. Ltd., Denver, CO)

ExoAtlet-II was cleared for marketing in 2021 via the 510(k) process (K201473). The FDA concluded that this device was substantially equivalent to existing devices, Ekso™ (version 1.1) and Ekso GT™ (version 1.2) (Ekso Bionics, Inc.). The ExoAtlet-II is intended to perform ambulatory functions in *rehabilitation institutions* under the supervision of a trained physical therapist for the following population with upper extremity motor function at least 4/5 in both arms:

- Individuals with SCI at levels T4 to L5, or
- Individuals with SCI at levels of C7 to T3 (ASIA D).

Indego® (Parker Hannifin, Cleveland, OH)

Indego was cleared for marketing in 2016 via the 510(k) process (K152416). The FDA concluded that this device was substantially equivalent to existing devices, citing ReWalk as a reference device. Indego is “intended to enable individuals with SCI at levels T7 to L5 to perform ambulatory functions with supervision of a specially trained companion.” Indego has also been granted marketing clearance for usage in *rehabilitation facilities.*

HAL for Medical Use (Lower Limb Type) (CYBERDYNE Inc.)

HAL for Medical Use (Lower Limb Type) was authorized for marketing by the FDA in 2017 through the 510(k) process (K171909). The predicate device was ReWalk. HAL is classified by the FDA under both Neurological Devices §21 CFR 882.5050 and Physical Medical Devices §21 CFR 890.3480 categories. The HAL is intended for use in *medical facilities* under the supervision of experienced medical personnel by patients with spinal cord damage at levels C4 to L5 (ASIA C, ASIA D) and T11 to L5 (ASIA A with Zones of Partial Preservation, ASIA B).

Keeogo™ Dermoskeleton System (B-Temia)

The FDA cleared the Keeogo exoskeleton for marketing in 2020 via the 510(k) process (K201539). The predicate device was the Honda Walking Assist Device. Keeogo is intended for use in stroke patients *undergoing rehabilitation.*

COVERAGE POLICY

The robotic lower body exoskeleton devices (e.g., ReWalk™; Ekso™/Ekso GT™; Indego; ExoAtlet-II; HAL; Keeogo) wearable lower-limb robotic exoskeleton **is considered experimental, investigational, and unproven** for use in lower limb paraplegia due to insufficient evidence in the high-quality peer-reviewed medical literature.

The evidence is largely limited to small case series, cohort or pilot studies for individuals in institutional settings with SCI patients. These studies evaluated the user's ability to complete common tasks under close supervision (e.g., Timed Up & Go test, 6-minute walk test, 10-meter walk test). The Veterans Administration concluded in a study published (2016) that more than 60 training sessions may be required to achieve proficiency with both indoor and outdoor mobility, including door/threshold navigation, halting, turning, and reaching (Asselin et al. 2016). Additional research is required to determine whether these devices can be used safely and efficiently outside of an institutional setting. The evidence is currently insufficient to determine that the technology results in an improvement in the net health outcome.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The clinical utility and beneficial health outcomes of robotic lower body exoskeleton devices is primarily limited to small studies or case series. Insufficient evidence exists to assess safety (outside of a medical or institutional setting, such as the risk of tripping and falling), long-term durability, tolerability, or improvements in net health outcomes.

ReWalk™

There is a paucity of published clinical data on ReWalk. The best available published evidence is limited to a cross-sectional study (n=9) (Fineberg et al., 2013), one open noncomparative nonrandomized study (n=12) (Esquenazi et al., 2012); one longitudinal prospective self-controlled feasibility study (n=60); 3 case series studies (n=8; n=12; and n=6) (Zelig et al., 2012; Spungen et al., 2013; Asselin et al. 2015); a systematic review and meta-analysis (Miller et al., 2016). There are no randomized controlled trials (RCT) comparing exoskeletons to wheelchairs and none of the studies were carried out in a home-setting or assessed long-term performance. A summary of the published literature is outlined below. Additional studies are needed to establish the safety and efficacy of these devices.

Zelig et al., (2012) assessed the safety and tolerability of the ReWalk (ReWalk Robotics, Inc., Marlborough, MA) exoskeleton ambulation suit in a small case series of six subjects with complete motor SCI between T5 and T12. Measures of functional ambulation were also assessed and correlated to neurological spinal cord level, age, and duration since injury. Pain and fatigue were graded by the participants using a visual analogue scale pre- and post-training. Participants completed a 10-statement questionnaire regarding safety, comfort, and secondary medical effects. After being able to walk 100 m, timed up and go, distance walked in 6 minutes and 10-m timed walk were measured. There were no adverse safety events. The system was generally well-tolerated, with no increase in pain and only a moderate level of fatigue after use. Individuals with lower levels of SCI walked more efficiently. The authors concluded that volunteer participants were able to ambulate with the ReWalk for a distance of 100 m with no adverse effects after an average of 13 to 14 training sessions. The system was generally well received by the participants. The authors stated that the ReWalk has many potential benefits, including improved functional mobility, cardio-vascular and respiratory status, bone metabolism, bowel and bladder function, and reduction of spasticity and neuropathic pain, but efficacy must be demonstrated in a larger study. Furthermore, the researchers noted that this study did not include any female subjects, people with tetraplegia, children, or elderly people; future large-scale inclusive studies are required.

Esquenazi et al. (2012) conducted a small open, noncomparative, nonrandomized study of 12 paraplegic subjects with thoracic level (T3-T12) SCI to assess the safety and efficacy of ReWalk in in enabling individuals with paraplegia due to SCI to perform routine ambulatory functions. After 8 weeks of acclimation training consisting of 24 60- to 90-minute sessions, all subjects were able to independently transfer and walk in the ReWalk for 50 to 100 m continuously for 5 to 10 minutes at speeds ranging from 0.03 to 0.45 m/sec (mean of 0.25 m/sec). Excluding two subjects with significantly diminished walking abilities, average distances and speeds improved substantially. Some subjects reported improvements in pain, bowel and bladder function, and spasticity during the trial. All subjects had strong positive comments regarding the emotional/psychosocial benefits of the use of ReWalk. The authors concluded that ReWalk has considerable potential as a safe ambulatory powered orthosis for motor-complete thoracic-level SCI patients. Most subjects achieved a level of walking proficiency comparable to that required for limited community ambulation. Individuals' performance varied greatly. Some of this variation can be explained by the severity of the injury, but other factors remain unknown. Further development and application of this rehabilitation tool to other diagnoses are anticipated.

Esquenazi et al., (2013) published a small, randomized, comparative trial with 16 participants with traumatic brain injury (TBI). This study compared the use of the ReWalk device versus manual treadmill rehabilitation training (n=8). The average self-selected walking velocity (SSV) increased by 49.8% for the ReWalk group (p=0.01) and by 31% for the manual group (p=0.06) following training. Average maximal velocity increased by 14.9% in the ReWalk group (p=0.06) and by 30.8% in the manual group (p=0.01). During SSV, the ratio of step-length asymmetries improved 33.1% for the ReWalk group (p=0.01) and 9.0% for the manual group (p=0.73). The ReWalk group increased their walking distance by 11.7% (p=0.21) while the manual group increased their walking distance by 19.3% (p=0.03). While each group showed benefits from their assigned training method, no differences were reported between groups. Given these results, the value of the ReWalk system in TBI rehabilitation training is uncertain.

Fineberg et al., (2013) conducted a small cross-sectional study to compare vGRF during powered exoskeleton-assisted walking (ReWalk™: Argo Medical Technologies, Inc, Marlborough, MA, USA) to vGRF of able-bodied gait. Six participants with thoracic motor-complete SCI (T1-T11 AIS A/B) and three able-bodied volunteers matched for age, height, weight, and gender participated in the study. Participants with SCI injuries were trained to ambulate over ground using a ReWalk™. vGRF was captured by the F-Scan™ system (TekScan, Boston, MA, USA). Peak stance average (PSA) was computed from vGRF and normalized by percent body weight across all participants. The peak vGRF was determined for heel strike, mid-stance, and toe-off. Relative linear impulse and harmonic analysis provided quantitative support for powered exoskeletal gait analysis. Participants with motor-complete SCI who ambulated independently with a ReWalk™ exhibited mechanical loading magnitudes and patterns comparable to able-bodied gait. Harmonic analysis of the PSA profile by Fourier transform contrasted the frequency of stance phase gait components between able-bodied walking and walking with an exoskeleton. Powered exoskeleton-assisted walking generated vGRF similar in magnitude and pattern to that of able-bodied walking in individuals with motor-complete SCI. The study suggests that powered exoskeleton-assisted walking has the potential to provide a mechanism for mechanical loading to the lower extremities. vGRF profile can be used to examine both magnitude of loading and gait mechanics of powered exoskeleton-assisted walking among participants of different weight, gait speed, and level of assist.

Spungen et al., 2013 reported the outcomes of a pilot study conducted at the Bronx Veterans Affairs Hospital to test the ReWalk system on 7 paraplegic SCI patients with permanent paralysis and mobility impairment. The study was not published in a peer-reviewed medical journal, but it was made available on the Department of Veterans Affairs website. This pre/post intervention pilot case series determined the number of sessions and level of assistance required to perform standing, walking, and stair climbing skills with the ReWalk device. On average, subjects participated in 45 20 sessions consisting of 1 to 2 hours of standing and overground ambulation for 3 sessions per week. All 7 participants were able to perform sit-to-stand, stand-to-sit, and ambulation from 50 to 166 m in 6 minutes with no (n=4) or varying (n=3) assistance. Four participants were able to ascend and descend 5 steps with assistance. These same 4 subjects have also developed outdoor-specific walking skills. According to the authors, there was no correlation between the acquisition of exoskeletal-assisted mobility skills and the severity or duration of SCI.

Asselin et al., (2015) reported the findings of a small case series involving 8 non-ambulatory subjects with paraplegia who have been trained to walk using the ReWalk device. The authors reported that the average value of oxygen update (VO2) during walking with the device was significantly higher for all subjects than when they were sitting or standing ($p<0.001$). In addition, the heart rate response during walking with the device was significantly higher than when subjects were sitting or standing ($p<0.001$). These results are consistent with what is commonly known about the physiology of the human body. Individuals with paraplegia are able to ambulate efficiently using the powered

exoskeleton for overground ambulation, providing the potential for functional gain and improved fitness. This study provided no information regarding the device's safety.

Asselin et al. (2016) published a study on the selection criteria, fitting, and training processes for using a powered exoskeleton for The Department of Veterans Affairs. Standing, sitting, and standing balancing exercises, advancement with inside and outdoor walking, and tasks requiring reaching, halting, turning, and door/threshold navigation were all practiced. At least 60 training sessions per patient were conducted during training sessions that lasted 60 to 90 minutes, three times per week.

Benson et al., (2016) performed a longitudinal, prospective, self-controlled feasibility study to assess the feasibility of conducting a well-powered trial evaluating the neurological and functional effects of using an exoskeleton in individuals with chronic SCI. Out of 60 candidates, 10 (17%) were enrolled and 5 (8%) completed the training program. Primary reasons for not enrolling were ineligibility (n = 24, 40%) and limited interest to engage in a 10-week training program (n = 16, 27%). Five out of 10 enrolled subjects experienced grade I/II skin aberrations. While walking speeds were higher and walking distances were longer in all exoskeleton users when compared with non-use, the exoskeleton did generally not meet subjects' high expectations in terms of perceived benefits. The conduct of a controlled trial evaluating the benefits of using exoskeletons that require a lengthy user-commitment to training of individuals with chronic motor complete or incomplete SCI comes with considerable feasibility challenges. Vigilance is required for preventing and detecting medical complications in SCI exoskeleton users.

Indego® (Parker Hannifin, Cleveland, OH)

Tefertiller et al. (2017) published the results of a case series study that included 32 participants with T4 and lower SCI. All subjects received training sessions with the Indego device 3 times per week for 8 weeks, with a single follow-up phone call one week after the training sessions ended. The trial was completed by all subjects. There were 11 documented device-related adverse events, including minor skin abrasions, joint swelling, and bruises. A trochanteric blister and an ankle sprain were the only two moderate adverse events. There were no changes in mid-study and final measures of indoor and outdoor 10MWT speeds (p=0.081 and p=0.62, respectively). On the 10MWT, average indoor walking speed improved by 0.06 m/s (SD=0.07) from mid-study to end assessments. Outdoor walking speed increased by 0.05 m/s (standard deviation = 0.08). Walking distance on the 6MWT increased for all subjects, with an average of 151 m from mid-study to final assessments.

Hartigan et al. (2015) conducted a case series study with 16 SCI patients to evaluate mobility results after 5 sessions of training. All individuals performed five 90-minute Indego exoskeleton training sessions followed by the 10MWT and 6MWT with the Indego devices and an assistive device. During the training sessions, additional outdoor tasks were evaluated, including walking on sidewalks, up and down Americans with Disabilities Act (ADA) compliant ramps, and over grass. 3 individuals had C5-C7 motor full quadriplegia, 5 had upper paraplegia, and 8 had lower paraplegia. Half of the individuals could walk indoors, outdoors, in elevators, and on ramps with minimum or moderate assistance. In a 6MWT, quadriplegics covered 64 m, upper paraplegics 76 m, and lower paraplegics 121 m. Seven subjects may individually don and doff the system.

Ekso (version 1.1) and Ekso GT (version 1.2)

Bach Baunsgaard et al. (2018) reported the results of a case series study of 52 people with SCI who were evaluated using the Ekso (n=8) and Ekso GT (n=44) devices. Subjects either sustained a complete motor injury from C7 to L2 or an incomplete motor damage from C1 to L2. The study included gait training sessions scheduled 3 times per week for 8 weeks, followed by 4 weeks of follow-up. The analysis included only participants who attended at least 16 of the 24 scheduled sessions. Eight patients (15.4%) withdrew from the study, and one was eliminated because to spasticity unrelated to the medication, leaving 42 evaluable subjects (80.8%) in the final analysis. Time to rise from a seated position, 10MWT, and the number of steps taken all increased considerably throughout the 8-week training period (p0.001 for all measures). As evaluated by the Borg Scale, the rate of perceived exertion also increased significantly (p=0.001). In the group of newly injured patients (less than one year since injury), the number of those with gait function rose from 5 to 14 after 8 weeks and to 15 after an additional 4 weeks. At the time of follow-up, a single participant in the chronically damaged group (less than one year since injury) had acquired gait function. No significant adverse events were reported, but "a number of skin concerns" were noted. They concluded that training with Ekso and Ekso GT was safe and practicable in a heterogeneous group of SCI patients and may improve gait function and balance.

Molteni et al. (2017) presented the first study on powered exoskeletons, which included 23 stroke patients who utilized the Ekso device in 12 one-hour sessions spread over four weeks (3 sessions per week). The authors stratified their data by subject condition, with 12 subacute (<180 days from the acute event) and 11 chronic (>180 days) cases. Motricity index (MI) total scores improved significantly after 6 and 12 weeks in the subacute group. MI measurements for the hip and knee at 6 and 12 weeks likewise revealed substantial benefits. At 12 weeks, there were significant improvements in the ankle level of MI. The Trunk Control Test (TCT) revealed substantial changes at 6 and 12 weeks. The Functional Ambulation Scale (FAC) had comparable outcomes. Two once immobile patients have attained ambulation. The 10MWT and the number of steps did not show any meaningful improvement. In this group, walking velocity and the 6MWT improved significantly at 6 and 12 weeks. The Ashworth scale, which evaluates lower limb spasticity, did not reveal any significant improvements in the chronic group. The total MI score improved significantly at 6 and 12 weeks only at the hip, but not at the knee or ankle. There were no major changes reported for the TCT, the 10MWT, or the actions implemented. At 12 weeks, FAC findings improved significantly, as did walking velocity at both time intervals and 6MWT outcomes.

Karelis et al., (2017) performed a small cohort study with 5 individuals with traumatic C7-T10 SCI and mild spasticity. All subjects went through a 6-week training phase that included three 3-hour training sessions per week with the Ekso device. Following the completion of the training sessions, no changes in the American Spinal Injury Association Impairment Scale (AIS) were noted. Significant changes in leg and appendicular lean body mass and total leg and appendicular fat mass were observed. The total BMI climbed noticeably. There are no reports of significant injuries.

Stampacchia et al. (2016) published the results of a cohort study investigating the impact of the Ekso GT™ exoskeleton system (Ekso Bionics, Inc., Richmond, CA) on pain and spasticity in 21 participants with partial or total SCI caused by traumatic or non-traumatic lesions. All subjects received a single 40-minute session of sitting to standing to walking with the Ekso device and an assisted walking device. Subjects completed a subjective rating scale (1 to 10) evaluating both pain and spasticity before and after the session. Spasticity was also assessed using the Modified Ashworth Scale (MAS) and the Penn Spasm Frequency Scale. Based on walking time and number of steps taken, walking behavior was determined to be homogeneous throughout the sample. A subjective rating scale, the MAS, and the PSFS scales all showed a substantial improvement in perceived spasticity after the walking session. Overall, perceived pain did not alter considerably, although significant pain reductions were noted in the subset of patients who had experienced pain before the session. There was no association between the pain decrease and spasticity reduction.

Sczesny-Kaiser et al. (2019) published the results of the HALESTRO study (HAL-Exoskeleton STROke study). 18 individuals with partial hemiparesis due to a stroke were enrolled for 6 weeks of HAL®-assisted (Cyberdyne, Tsukuba, Japan), supervised, body weight supported treadmill exercise. In this crossover trial, participants also underwent six weeks of conventional physiotherapy (CPT). There were no statistically significant differences between the HAL-BWSTT group and the CPT group for the 10MWT (p=0.071), 6MWT (p=0.840), or TUG (p=0.835). In comparison to CPT, the authors found that HAL-BWSTT did not significantly enhance walking function or balance. There is potential in the combination of therapies; however additional studies are required to evaluate health outcomes. Compared to the standard of care, the trial was small and lacked the necessary follow-up to determine if the increase in motor capacities was durable or continued.

Systematic Review and Meta-Analysis

Hayes et al. (2018) published the findings of a systematic review of robotic exoskeleton devices used in SCI gait training. There were 12 studies total, 3 of which were overground trials, and 9 of which involved treadmill trials. Walking speed and walking distance were the primary outcome measures reported. The use of a treadmill or overground-based robotic exoskeleton-assisted gait training did not result in a greater gain in walking speed than conventional gait training, according to the findings. In addition, the review concluded that none of the assessed studies resulted in an improvement substantial enough to support community ambulation.

The Cochrane Library published a report (2017) that reviewed electromechanical-assisted training for walking after stroke. The study concluded that patients who undergo electromechanical-assisted gait training in conjunction with physiotherapy after a stroke are more likely to attain independent walking than people who receive gait training without these devices. It was concluded that 7 patients must be treated in order to prevent 1 dependency in walking. People in their initial 3 months after a stroke, as well as those who are unable to walk, appear to benefit the most from this form of intervention. The function of the sort of device is currently unknown. Large, conclusive, and pragmatic phase 3 studies should be conducted to address specific issues regarding the most effective frequency and duration of electromechanically assisted gait training, as well as the duration of any potential benefits.

Miller et al., (2016) conducted the first meta-analysis of the available published research on the clinical effectiveness and safety of powered exoskeletons in SCI patients. Main outcomes were analyzed using fixed and random effects meta-analysis models. A total of 14 studies (eight ReWalk™, three Ekso™, two Indego®, and one unspecified exoskeleton) representing 111 patients were included in the analysis. Training programs were typically conducted three times per week, 60-120 minutes per session, for 1-24 weeks. Ten studies utilized flat indoor surfaces for training and four studies incorporated complex training, including walking outdoors, navigating obstacles, climbing and descending stairs, and performing activities of daily living. Following the exoskeleton training program, 76% of patients were able to ambulate with no physical assistance. The weighted mean distance for the 6-minute walk test was 98 m. The physiologic demand of powered exoskeleton-assisted walking was 3.3 metabolic equivalents and rating of perceived exertion was 10 on the Borg 6-20 scale, comparable to self-reported exertion of an able-bodied person walking at 3 miles per hour. Improvements in spasticity and bowel movement regularity were reported in 38% and 61% of patients, respectively. No serious adverse events occurred. The incidence of fall at any time during training was 4.4%, all occurring while tethered using a first-generation exoskeleton and none resulting in injury. The incidence of bone fracture during training was 3.4%. These risks have since been mitigated with newer generation exoskeletons and refinements to patient eligibility criteria. In conclusion, powered exoskeletons allow patients with SCI to safely ambulate in real-world settings at a physical activity intensity conducive to prolonged use and known to yield health benefits.

National and Specialty Organizations

The **American Physical Therapy Association** published guidelines (2020) with recommendations for the improvement of locomotor function in ambulatory patients following brain injury, stroke, or incomplete SCI. The guidelines discourage the use of powered exoskeletons for usage on a treadmill or elliptical to improve walking speed or distance following an acute-onset central nervous system injury in patients who are more than 6 months post-injury due to minimal benefit, increased costs, and increased time.

The **American Heart Association and the American Stroke Association** published guidelines (2016) for adult stroke rehabilitation and recovery (Winstein, 2016). The guidelines addressed the use of robotic and electromechanics-assisted training devices, and concluded that “Overall, although robotic therapy remains a promising therapy as an adjunct to conventional gait training, further studies are needed to clarify the optimal device type, training protocols, and patient selection to maximize benefits.”

SUPPLEMENTAL INFORMATION

American Spinal Cord Injury Association (ASIA) Impairment Scale: A universal classification tool for SCI based on a standardized sensory and motor assessment, with the most recent revision published in 2019.

CODING & BILLING INFORMATION

CPT Codes – N/A

HCPCS	Description
K1007	Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors
L2999	Lower extremity orthoses, not otherwise specified [when specified as a powered robotic lower body exoskeleton device]

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/12/2022	Policy revised. Expanded scope of policy and updated title **from** 'Lower-Limb Robotic Exoskeleton (ReWalk-P [Personal]) for Paraplegia in Spinal Cord Injury' **to** 'Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities (ReWalk).' No changes in coverage position. IRO reviewed by Physical Medicine and Rehabilitation. Notable revisions include: • Revised policy to include FDA-approved powered exoskeletons, in addition to ReWalk, and expanded scope of policy from paraplegia in spinal cord injury to patients with lower-limb disabilities. • Added related, relevant clinical studies in 'Summary of Medical Evidence' section. • Added clinical practice guidelines (American Physical Therapy Association and American Heart Association and the American Stroke Association)
10/13/2021	Policy reviewed, no changes to criteria updated references, added new HCPCS K1007 and removed L2999.
9/16/2020	Policy reviewed, no changes, updated references.
9/18/2019	Policy reviewed, no changes.
3/8/2018	Policy reviewed, no changes to criteria, updated Summary of Medical Evidence and references. IRO review on February 1, 2018 by practicing, board-certified physician(s) in Pain Management and Physical Medicine and Rehabilitation.
12/16/2015, 12/14/2016, 6/22/2017	Policy reviewed, no changes.
8/5/2015	New policy.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search terms: robotic wearable exoskeletons; ReWalk Personal System). Available from CMS. Accessed September 2022.
2. United States Food and Drug Administration (FDA). Evaluation of automatic class iii designation (De Novo) for Argo Rewalk™: de novo summary no. K131798. Available from FDA. Published June 22, 2013. Accessed September 2022.
3. United States Food and Drug Administration (FDA). 510(k) Premarket Notification Database.
   - Ekso and Ekso GT. No. K143690. Richmond, CA: FDA. April 01, 2016. Available from FDA.
   - ExoAtlet-II. Available at: FDA.
   - HAL for Medical Use (Lower Limb Type). No. K171909. Tsukuba, Japan. Available from FDA.
   - Indego. No. K171334. Austin, TX. Available from FDA.
   - ReWalk. No. K131798. Marlborough, MA. Available from FDA.
   - Keeogo Dermoskeleton System. Available from FDA.

Evidence Based Reviews and Publications

1. Hayes. Evidence analysis research brief: ReWalk personal system for home use in spinal cord injury. Available from Hayes. Published July 16, 2020. Archived August 16, 2021. Registration and login required.
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Peer Reviewed Publications

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*